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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,366	01/23/2006	Rolf Hartung	7601/8-4486	5556
66991 7590 11/23/2010 LAW OFFICE OF MICHAEL A. SANZO, LLC 15400 CALHOUN DR. SUITE 125 ROCKVILLE, MD 20855				
EXAMINER YOUNG, SHAWQUITA				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
11/23/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,366

Applicant(s)

HARTUNG ET AL.

Examiner

SHAWQUA YOUNG

Art Unit

1626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28 and 32-47 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 28-47 are currently pending in the instant application. Claims 28 and 32-47 are rejected and claims 29-31 are objected in this Office Action.

I. *Response to Arguments/Remarks*

Applicant's arguments, filed September 10, 2010, with respect to the rejection of claims 28 and 32-47 under 35 USC 103 as being unpatentable over Minnaard, et al. in view of Schuda, et al. have been fully considered and are not found to be persuasive. Applicants have requested that the Examiner provide an explanation of why the pending 103 rejection was introduced, withdrawn and then reintroduced. The reason is because the Examiner withdrew the rejection previously in error. Applicants provided mere arguments on August 14, 2009 arguing the differences between the instant invention and the prior arts' teachings. For example, using a rhodium catalyst, Minnaard reports a 92% yield after a reaction of 40 hours and using a platinum catalyst, Schuda reports a reaction that proceeds for 18 hours and that appears to produce a yield of 98%. Whereas the same types of products under similar conditions, Applicants report yields of 94.2%-98.6% after reaction times that are less than half of those reported in the references. The Examiner wants to point out that merely modifying the process conditions which includes concentration, temperature, reaction times, etc. is not a patentable modification absent a showing of criticality (See *In re Aller*, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955)). Further, Applicants have not provided comparative data in the originally filed specification or in a declaration showing unexpected results. Mere

arguments are not enough to show unexpected or unobvious results. According to MPEP 716.01(b), attorney's arguments cannot take the place of evidence on the record. And if Applicants want to show unobvious or unexpected results, they are suggested to show the unobvious or unexpected results in the form a declaration. The reasons above are why the Examiner has reintroduced the pending 103 rejection and why Applicants' arguments filed on September 10, 2010 do not overcome the rejection. The Examiner has maintained the rejection in this Office Action claims 28 and 32-47. The Examiner has withdrawn the 103 rejection of claims 29-31 because claims 29-31 are drawn to subset of compounds that are not taught in the prior art references.

II. ***Rejection(s)***

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

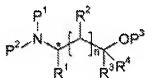
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. § 103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28 and 32-47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Minnaard, et al.* (Synthetic communications, 29, 1999) in view of *Schuda, et al.* (J. Org. Chem. 1988, 53). Applicants claim a process for the hydrogenation of a compound, comprising hydrogenating a C₆-C₁₈ aromatic substituted amino acid or C₆-C₁₈ aromatic substituted amino alcohol in the presence of a platinum-rhodium mixed catalyst, wherein said amino acid or amino alcohol is of the formula



wherein all variables are as defined in claim 28 and wherein said process produces a yield of greater than 94% after a reaction time of about 6 to 8 hours. Claim 41 is drawn to a process for the hydrogenation of a compound selected from the group consisting of : L-phenylalanine, D-phenylalanine, L-phenylglycine, D-phenylglycine, L-tyrosine or D-tyrosine, comprising hydrogenating said compound in the presence of a platinum-rhodium mixed catalyst wherein said process produces a yield of greater than 94% after a reaction time of about 6 to 8 hours.

The Scope and Content of the Prior Art (MPEP §2141.01)

Minnaard, et al. teaches the synthesis of enantiomerically pure cyclohexylglycine by hydrogenating phenylglycine using a rhodium catalyst and rhodium catalyst on support. The reaction resulted in a high yield and no racemization occurred. The prior art reference also teaches the use of palladium, platinum or ruthenium as catalysts in the synthesis.

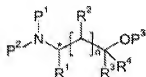
Schuda, et al. teaches the hydrogenation of L-phenylalanine by using a platinum catalyst (i.e. PtO₂) and the reaction result in a high yield and does not undergo racemization.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Minnard, et al.* in view of *Schuda, et al.* and the instant invention is that the instant invention uses a mixed platinum-rhodium catalyst whereas the prior art teaches the use of platinum and rhodium separately.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

Applicants are claiming a process for the hydrogenation of a compound, comprising hydrogenating a C₆-C₁₈ aromatic substituted amino acid or C₆-C₁₈ aromatic substituted amino alcohol in the presence of a platinum-rhodium mixed catalyst, wherein said amino acid or amino alcohol is of the formula



wherein all variables are as defined in claim 28. Claim 41 is

drawn to a process for the hydrogenation of a compound selected from the group consisting of : L-phenylalanine, D-phenylalanine, L-phenylglycine, D-phenylglycine, L-tyrosine or D-tyrosine, comprising hydrogenating said compound in the presence of a platinum-rhodium mixed catalyst. The prior art teaches a similar process wherein either a platinum catalyst or a rhodium catalyst is used and both catalyst are successful in the hydrogenation reaction.

In In re Crockett, et al., 126 USPQ 186, it was well established that when the prior art teaches the use of two catalysts, the idea of combining them would flow logically from prior art and claim to joint use is not patentable. Also, it was well established the selection of reaction conditions (i.e., temperature, concentration, reaction times, etc.) is more optimization by mere modification of routine experimentation and within one skilled in the art. So Applicants modifying the reaction time to about 6 to 8 hours vs. for example, 18 hours as seen in the prior art, is considered mere modification of routine experimentation and within one skilled in the art. For example, it is obvious to combine rhodium and platinum catalysts in a hydrogenation process of aryl substituted amino acids when the art teaches the use of each catalyst separately in the same type of reaction with reasonable expectation of success. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to use a mixed platinum-rhodium catalyst in the hydrogenation of a compound according to claim 28 or 41 based on the teachings in the prior art. A strong prima facie obviousness has been established. Applicants are suggested to provide a showing of

unexpected results in the form of a declaration to overcome the 103 rejection.

III. Objection

Dependent Claim Objections

Dependent Claims 29-31 are objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

IV. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626